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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/890,029

Filing Date: July 24, 2001

Appellant(s): BOGYE, GABOR

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For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 23, 2007 appealing from the Office action mailed May 4, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

Upon reconsideration, the rejection under 35 USC 112, second paragraph of claim 39 with regard to the limitation "for contraception" is withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Spellacy et al., Contraception, 1972;6(4):263-273

Butterworth et al., Am. J. Clin. Nutr. 1982;35(1):73-82

6,190,693 Kafrissen et al. 2-2001

5,654,011 Jackson et al. 8-1997

html version of Fermo et al., Annals of Internal Medicine, 1995;123(10):747-753,
at <http://www.annals.org/cgi/content/full/123/10/747>

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20, 26-28, 32, 33, 34, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "an otherwise healthy patient" recited in claim 20 renders the claims indefinite as to the patient population encompassed thereby. It is not clear what patients or individually would be considered "healthy" as recited in the claims. Is patients experiencing side effect from the medication considered "healthy"? For example, if a patient takes progesterone composition and experience headache or depression after taking the medication, is she a

"healthy" patient? The metes and bounds of the claims are not clear.

Furthermore, are they otherwise healthy if no medication was taken (including the hormonal composition)? Or does the term mean that the patients are healthy if no plasma homocysteine reducing agents are taken?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20, 28, 29, 31, 32, 33, 35, 37, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Spellacy et al. (Contraception, 1972;6(4):263-273), reference of record.

Spellacy et al. teaches vitamin B6 supplement is administered to women taking progesterone containing oral contraceptive (See the abstract).

Claims 20, 27, 32, 33, 34, 35, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Butterworth et al. (Am. J. Clin. Nutr., 1982;35(1):73-82 from IDS received 1/2/2002).

Butterworth et al. teaches folic acid was supplemented to women taking progesterone containing oral contraceptive (See the abstract).

Claims 9, 11, 20, 27, 32-36, and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Kafrissen et al. (US Patent 6,190,693).

Kafrissen et al. teaches a method of administering folic acid along with either oral contraceptives containing progesterone or hormone replacement therapy containing progesterone (See for example claims 5 and 8). Kafrissen et al. also teaches the amount of folic acid employed as 25microgram to 1gram to reducing homocyteine level (See col. 7, lines 55-56).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9-12, 20, and 25-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (US Patent 5,654,011) in view of Fermo et al. (Annals of Internal Medicine, 1995;123(10):747-753 – html version).

Jackson et al. teaches a multivitamin composition containing homocysteine level reduction amount of folic acid, vitamin B6, and vitamin B12 (See col. 3, line 60-63, col. 5, lines 15-30, col. 6, lines 18-21). Jackson's composition is taught as useful inn various stages of women life for reducing health risks of women (See the abstract).

Jackson et al. does not expressly teach the patients taking hormonal composition containing gestagen.

Fermo et al. teaches hyperhomocysteinemia as pathogenic significant of patients developing thrombosis (See the abstract and the Discussion Section).

It would have been obvious to one of ordinary skill in the art at the time of invention to employ folic acid, vitamin B6, and vitamin B12 to reduce the serum level of homocysteine and thereby the risk of coronary disease in patients taking gestagen composition.

One of ordinary skill in the art would have been motivated to employ folic acid, vitamin B6, and vitamin B12 to reduce the serum level of homocysteine and thereby the risk of coronary disease in patients taking gestagen composition. It

is known that high homocysteine level is associated with coronary diseases including thrombosis. Therefore, employing a homocysteine reducing amount of vitamin B6, B12, and folic acid, regardless of what the cause of hyperhomocysteinemia or patient population might be, to any patient suffering from hypercysteinemia including patient population herein recited, would be reasonably expected to be useful and effective in lowering the homocysteine level and further reducing the risk of thrombosis thereby.

(10) Response to Argument

Appellant's arguments on pages 4-6 of the Brief filed January 23, 2007 averring the skilled artisan would have known what the metes and bounds of the term "otherwise healthy patients" encompassed. The examiner submits that there are at least two meanings of such term when it is recited in the way it is in the instant claims. The first is the ordinarily meaning of the term, which the appellant has explained very well. The second meaning of such term as it is recited in the instant claims could mean that the patient is healthy except for having thromboembolism. Therefore, the Examiner raised a question in the rejection under 35 USC 112, second paragraph asking 'if a patient takes progesterone composition and experience headache or depression after taking the medication, is she a "healthy" patient?' since he/she does not experience thromboembolism when he/she is taking the hormone preparations. The instant specification does not make clear what such term means. Accordingly, the examiner believes that the rejection should be affirmed.

Appellant's arguments on pages 7-14 of the Brief filed January 23, 2007 averring Kafrissen et al. not anticipating the instant claims are not convincing. Especially, appellant argues, "The method of KAFRISSEN et al. relates to patients who are afflicted with or predisposed to become afflicted with a disorder due to which they have to be steadily treated with folic acid" [emphasis added] (see page 7, second paragraph). The examiner notes that there is no teaching in Kafrissen et al. teaching such fact. The method of Kafrissen et al. rather relates to a method of treating or preventing a disorder **treatable or preventable** by (not caused by or due to) the administration of folic acid. The examiner further notes that the patients in Kafrissen et al. are administered with folic acid prior to having any disorders (see for example col. 2, line 66 bridging col. 3, line 23). Attention is directed to the disclosure in col. 3, lines 7-14, stating that the method comprising the administration of (a) hormonal replacement composition and (b) folic acid in an amount sufficient to treat or **prevent** a disorder... When the method of Kafrissen et al. is to prevent the disorder from happening, the patients are clearly free of such disorder. In other words, if the patients have already had the disorder, prevention of such disorder is moot. Even when the patients are predisposed to the disorder, they are **not** having such disorder. Accordingly, it is clear that the patient population of Kafrissen et al. is the same as that of the instant invention despite appellant's attempt to use a linguistic slide of hands to distinguish the patient populations between the patient population of the instant invention and that of Kafrissen et al. The rejection under 35 USC 102(e) of instant claims over Kafrissen et al. should be affirmed due to inherency since

Kafrissen et al teaches the exact same method steps, i.e., administering the same compound (folic acid) to the same patient populations (individuals who take progestin hormone product).

Appellant further argues on page 7 that having "the risk factors of a disease is not equal to being healthy". The examiner would like to encourage appellant to support such assertion with evidence. It is well-known in the art that some risk factors of certain diseases can be another disorder itself. But some risk factors of certain diseases, especially cardiovascular diseases, can be merely being male gender. Some of the disorders are listed in col. 5, lines 46-49 and claim 6, cervical dysplasia, cervical carcinoma, and a cardiovascular disorder. As we can see from Butterworth for example, cervical dysplasia is associated with the use of hormonal contraceptives. Without specific evidence in Kafrissen et al., one cannot just assume having the predisposing factors equates to being unhealthy. One also cannot assume that the individuals in Kafrissen et al. are having unhealthy risk factor without any evidence showing that they do. Kafrissen et al. is silent with this regard and therefore the proper assumption is that the individuals do not have any unhealthy predisposing factors and that the individuals in Kafrissen et al. are healthy. Since there is no evidence showing the individuals in Kafrissen et al. as being unhealthy or having a predisposing factor that could be considered as being unhealthy, the rejection under 35 USC 102 (e) of instant claims over Kafrissen et al. should be affirmed due to inherency since Kafrissen et al teaches the exact same method steps, i.e., administering

the same compound (folic acid) to the same patient populations (individuals who take progestin hormone product).

Appellant's arguments on pages 14-16 of the Brief filed January 23, 2007 averring the submission of the declaration under 37 CFR 1.131 as sufficient to overcome the rejection under 35 USC 102(e) over Kafrissen et al. are not convincing. The examiner notes that in MPEP 706.02(b) (D), it essentially states that the rejection under 35 USC 102(e) cannot be overcome by a declaration under 37 CFR 1.131 as it is not sufficient to antedate the reference if it is a US patent and teaches the same invention. Accordingly, the rejection under 35 USC 102 (e) of instant claims over Kafrissen et al. should be affirmed due to inherency since Kafrissen et al teaches the exact same method steps, i.e., administering the same compound (folic acid) to the same patient populations (individuals who take progestin hormone product).

The examiner notes that the arguments with regard to the rejection under 35 USC 102(b) over Spellacy and Butterworth comprise essentially the same issue. Appellant argues that the patient populations are not the same in the cited prior art as that of the instant invention. Therefore, the method of the instant invention is not inherently present in that of the cited prior arts. Such arguments are not convincing as discussed below:

Appellant's arguments on pages 16-19 of the Brief filed January 23, 2007 averring the patients in the cited prior art as different from that of the instant invention are not convincing. The examiner submits that the crux of the arguments hinges on the interpretation of the term "otherwise healthy patient".

The examiner notes that the term is construed as an individual who is healthy without taking the hormonal composition. In the case of Spellacy and Butterworth, the hormone products are prescribed for contraception. Individuals (notes: not patients) who takes oral contraceptives are not trying to treat any diseases. Therefore, these individuals are healthy before taking the hormone oral contraceptives. Accordingly, the individuals disclosed in the cited prior arts are the very same patients of the instant invention.

Appellant's arguments on pages 19-23 averring the lack of teachings of the administration of gestagen hormone and its relationship between homocysteins levels and thromboembolism are not convincing. The herein claimed invention is directed towards the treatment of elevated homocysteine levels in order to reduce the risk of thromboembolism using old and well-known agents for reducing homocysteine levels due to gestagen hormone. The examiner notes that the herein claimed agents are known to decrease the level of homocysteine, which is responsible for increasing the risk of cardiovascular disorders. Therefore, one of ordinary skill in the art would have been motivated to employ the herein recited agents to treat the elevated homocysteine levels and thereby reduce the risk of thromboembolism in the same patients, regardless of the cause of elevated homocysteine level. Considering the following example: morphine, an old and well-known analgesic, is known to be effective to treat pain, regardless of what the causes might be, be it cancer related pain, pain due to broken bone, or pain due to kidney stone. These conditions can be effectively treated with morphine since the treatment is directed to pain itself and not the

Art Unit: 1617

etiologies of it. In the same way, the instant invention is to treat elevated homocysteine levels, not the etiologies (e.g., one of which is gestagen hormone according to the instant claim) of it. Therefore, when a patient is presented with elevated homocysteine levels, possessing the cited prior arts, one of ordinary skill in the art would have employed the herein claimed agents in a method of treating hyperhomocysteinemia and thereby reducing the risk of thromboembolism.

The examiner also acknowledges the arguments with regard to other etiologies of thromboembolism; however, since the arguments are not relevant to the basis of the rejection, they are considered moot. To clarify what the examiner means, please consider the following example: there are many mechanisms of action that can treat hypertension, e.g., blocking the calcium channel, blocking the β -receptor, blocking the angiotensin receptor, blocking the ACE (angiotensin converting enzyme), and diuretics (causing the loss of electrolytes and water to reduce the load and pressure). One of ordinary skill in the art would readily recognize that the treatment of hypertension does not need not to address every known mechanisms of action that reduces hypertension. In fact, clinicians usually prescribe a medication targeting one mechanism and that would be sufficient to treat the condition. In the same way, the lowering of homocysteine level is sufficient to reduce the risk of thromboembolism. One of ordinary skill in the art needs not to address every etiologies of thromboembolism. Accordingly, the rejection under 35 USC 103(a) should be affirmed.

Art Unit: 1617

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



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